The Challenge of High Drug Prices in America: Cost Disclosure in Direct-to-Consumer Advertising May Offer a Solution

By Kamille Garness, MD, MPH Candidate
Milken Institute School of Public Health, George Washington University, Washington, DC

Drug price disclosure in direct-to-consumer (DTC) advertisements is one of the best approaches to improving prescription drug market competition, which may also help mitigate the rising costs of medications for Americans. The high cost of pharmaceuticals continues to be one of the major financial burdens that Americans face today and creates barriers to medication access. According to the Centers for Disease Control and Prevention, almost 8% of Americans do not take their medications as prescribed because they cannot afford them.[1]

A recent consumer report survey indicated that 25% of Americans pay more out-of-pocket costs for medications today than they did a year ago.[2] The expanded use of cheaper generic drugs through the loss of patent exclusivity by brand-name drug companies and the emergence of biosimilar drugs are some of the ways that the rising out-of-pocket drug costs are being curbed. However, more can be done to address this issue by improving prescription drug cost transparency.

One way to improve transparency is by requiring drug manufacturers to disclose the cost of their medications in television advertisements. Disclosing drug prices in DTC advertisements will significantly improve drug price transparency. In October 2018, the Centers for Medicare & Medicaid Services (CMS) proposed a rule that would require drug manufacturers to disclose the wholesale acquisition cost (WAC) of a drug in television advertisements.[3] This rule was finalized in May 2019 and became active in July 2019 under the Trump administration, once a final decision was made after its release for public comment and review.[4]

Today, DTC advertising lacks transparency when it comes to the cost of prescription drugs sold to consumers. This lack of information on a drug's WAC, which is also known as the list price, limits the consumer's ability to make decisions about what medications to purchase, from whom to purchase them, and the prices they can expect to pay. The Department of Health & Human Services is now requiring that television advertisements include the list price for prescription and biologic drugs that are covered by Medicare and Medicaid if they cost more than $35 monthly.[5] A total of 47% of Americans currently pay the list price for drugs that are not covered by their health plans formulary until their health insurance begins paying for it, because of the high-deductible components of health plans.[5]

WACs provide an accurate judgment of the price paid by retail pharmacies and are useful for determining the best price or the average lowest wholesale price of single-source or brand-name drugs.[5] The United States, unlike many other Organisation for Economic Co-operation and Development countries (such as Australia), lacks universal healthcare insurance policies or benefit designs that limit out-of-pocket expenses.[6]

One of the main reasons for the high drug prices in the United States is a lack of price control mechanisms, such as centralized price negotiations for prescription drugs in other countries. Instead, the United States leaves drug pricing up to market competition, which makes it a very profitable market for pharmaceutical companies that can set their own prices without restrictions. The May 2019 final rule from CMS removed financial incentives for drug manufacturers to raise drug prices for additional profits, which can reduce the increasing costs of medications in the United States.[4]

In 2016, the national health expenditure on prescription drugs in the United States was approximately $332 billion, or almost 10% of the total healthcare spending.[7] By 2021, this number is expected to be more than $400 billion.[7] The United States is considered an outlier when its per-capita drug spending is compared with other high-income countries, such as Australia, Canada, France, and Germany.[6] In 2015, drug spending in the United States was 6 times higher than in these high-income countries and 16 times higher than in countries such as India.[8]

Furthermore, the high costs of rewarding research and development for drug innovation in the United States has left many Americans to believe that they are subsidizing health systems in other countries.[9] However, there is no evidence to support the idea that these so-called

foreign "free riders" enjoy the benefits of drug innovation without paying for its costs.[9]

Drug price disclosure will likely also improve market competition among drug manufacturers and will supplement existing drug policies, such as the 1984 Hatch-Waxman Act, which expanded the use of generic drugs and reduced anticompetitive behavior between brand-name and generic drug manufacturers. Although the US Food and Drug Administration (FDA) has no legal authority to regulate drug manufacturers' prices, it can encourage market competition for lower-priced prescription drugs. The FDA has proposed simple policy changes to do this, which have led to an increase in generic drug competition.

The implementation of the Drug Competition Action Plan by the FDA in 2017 has improved drug competition through the approval of more generic drugs and the reduction of monopoly pricing by brand-name drug manufacturers. The Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act, allows generic drug approvals under the Federal Food, Drug, and Cosmetics Act.[10-12] This law allows generic drugs to uphold that they are chemically similar to the FDA-approved innovator drug with analogous efficacy and safety, which allows for the expansion of generic drug manufacturers by providing incentives for the research and development of new drugs.[10]

Enforcing the disclosure of drug prices in DTC advertisements will continue to add to the objectives of the Drug Competition Action Plan. The bargaining power of generic drugs allows for the negotiated pricing of expensive brand-name drugs by improving market competition. Disclosing the WAC price for a drug could lead to the emergence of more affordable generic drugs for consumers as drug manufacturers compete to have the lowest-priced drug advertisements.[11]

Over the past few years, however, anticompetitive behaviors by brand-name drug manufacturers who try to delay the market entry of generic drugs have resulted in high drug prices, by reducing price competition.[11] The first example of this is the pay-for-delay techniques used by brand-name drug manufacturers who file suits against generic drug manufacturers for patent violations to extend periods without generic drug market competition.[11]

Another technique used by brand-name drug companies is "product hopping," in which drug companies reformulate a drug to extend its intellectual property protection rights and patent exclusivity, thereby preventing the entry of generic drugs and prolonging the period for monopoly pricing of these highly priced drugs.[11,13] Thus, we must continue to think of innovative ways to improve drug cost transparency to overcome these anticompetitive behavioral tactics.

Overall, the new ruling by CMS to mandate drug manufacturers to disclose drug prices in DTC advertisements[4] will likely be the next big step in improving drug price transparency in the United States. The market competition that will be created as a result of this new regulation could help to alleviate the high costs of drugs, reduce the financial incentives to drug manufacturers, and the subsequent financial barriers to accessing these medications for many Americans. Policymakers will need to move quickly to turn this rule into an obligation, because it will likely be one of the best solutions to limit the rapid growth of the US national health expenditure on medications, and to ensure that our citizens can access the affordable medicines they need to stay healthy.

Author Disclosure Statement

Dr Garness has no conflicts of interest to report.

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